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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,082	02/09/2005	Keith Alan Charlton	133088.00201(P35262US)	8653

35151 7590 09/08/2008

Pepper Hamilton LLP
400 Berwyn Park
899 Cassatt Road
Berwyn, PA 19312-1183

EXAMINER	
NAVARRO, ALBERT MARK	
ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
09/08/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/524,082	CHARLTON ET AL.	
	Examiner	Art Unit	
	Mark Navarro	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,6-12,17-20,24-29,32 and 33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *33* is/are allowed.

6)☒ Claim(s) *1,2,6-12,17-20,24-29 and 32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants amendment filed July 24, 2008 has been received and entered. Claims 3-5, 13-16, 21-23, and 30-31 have been cancelled; accordingly, claims 1-2, 6-12, 17-20, 24-29, and 32-33 are pending in the instant application.

Claim Rejections - 35 USC § 112

1. The rejection of claim 33 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is withdrawn in view of Applicants response that the deposit complies with the requirements of 37 CFR 1.801-1.809.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. The rejection of Claims 19-20, 24-29 and 32 under 35 U.S.C. 102(e) as being anticipated by Kende et al is maintained.

Note this rejection has been withdrawn from method claims 1-2, 6-13 and 17-18.

Applicants are asserting that they are unable to locate any portion of the Kende reference that teaches human antibodies that specifically target the free soluble form of the homoserine lactone molecule as recited by Applicants. Applicants further assert that their antibodies are achieved without the need for immunization as reported in the Kende reference, and thus Kende does not teach each and every limitation of the claimed invention.

Applicants arguments have been fully considered but are not found to be persuasive.

First, Applicants assert that they are unable to locate any portion of the Kende reference that teaches human antibodies that specifically target the free soluble form of the homoserine lactone molecule as recited by Applicants. However, Applicants are respectfully directed to detailed description paragraph 36, which sets forth that "the hybridoma technique of Kohler and Milstein, the trioma technique, the human B-cell hybridoma technique, and the EBV-hybridoma technique to ***produce human monoclonal antibodies*** may be used and can be obtained by using human hybridomas." (Emphasis added).

Second, the monoclonal antibody of Kende et al binds to the identical molecule N-butanoly-L-homoserine lactone. (See claim 4 of Kende et al vs. claim 2 of the instant application).

Finally, Applicants assert that their antibodies are achieved without the need for immunization as reported in the Kende reference, and thus Kende does not teach each and every limitation of the claimed invention. However, claims 19-20, 24-29 and 32 all claim a monoclonal antibody based on its method of production (e.g., selected from a human antibody phage display library). "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

The claims are drawn to a monoclonal antibody to a molecule of a homoserine lactone of Formula I, specifically N-butanoly-L-homoserine lactone, and methods of treatment of bacterial infection comprising administering said antibody.

Kende et al (US Patent Number 6,713,059) disclose of monoclonal antibodies to N-butanoly-L-homoserine lactone. (See claim 4). Kende et al further disclose of methods of treating or preventing an infectious disease comprising administering the antibody to a subject. (See paragraph 23). Kende et al futher disclose of single chain antibodies. (See paragraph 39).

Accordingly, Kende et al is deemed to anticipate the instantly filed claims.

For reasons of record as well as the reasons set forth above, this rejection is maintained.

The following new grounds of rejection are applied to Applicants amended claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-2, 6-12, 17-20, 24-29, and 32-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kende et al in view of McCafferty et al.

The claims are directed to a method for the treatment of a bacterial infection of a subject comprising administering to said subject a monoclonal antibody, wherein said monoclonal antibody is selected from a naïve human antibody phage display library by screening the library against a homoserine lactone molecule of Formula I, wherein said antibody specifically binds to the free soluble form of the homoserine lactone or a C_1-C_{10} saturated or unsaturated carboxylic acid derivative thereof in the presence of conjugated derivatives thereof.

The teachings of Kende et al are set forth above.

Kende et al do not teach of selecting a monoclonal antibody from a naive human antibody phage display library.

McCafferty et al (Nature Vol. 348, No. 6301, pp 552-554, Dec. 1990) teach that at the time of the instant application, it was routine to select monoclonal antibodies from a naïve human antibody phage display library. (See abstract).

Given that Kende et al have taught of methods for the treatment of a bacterial infection of a subject comprising administering a monoclonal antibody which binds a homoserine lactone molecule of Formula I, and that McCafferty et al have taught that it was routine in the art to select monoclonal antibodies from a naïve human antibody phage display library, it would have been prima facie obvious to have substituted a monoclonal antibody which binds a homoserine lactone molecule of Formula I from a naïve human antibody phage display library as taught by McCafferty et al for use in the method as taught by Kende et al.

The U.S. Supreme Court has very recently addressed the obviousness of a combination of known elements. A rigid application of the Court of Appeals for the Federal Circuit's "teaching, suggestion, or motivation" test was rejected, the Court stated that a "combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results. *KSR International Co. v. Teleflex Inc. et al.,* No. 04-1350, slip op. at 12 (S. Ct., April 30, 2007).

Claim 33 is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on (571) 272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark Navarro/
Primary Examiner, Art Unit 1645
September 4, 2008